Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

Protocol summary

Summary

This study is a randomized clinical trial to compare the effects of high-dose atorvastatin with low-dose atorvastatin on inflammatory markers and coagulation profiles in patients with type 2 diabetes. patients with type 2 diabetes over the age of 18 , LDL> 70 and TG <500 , patients are not treated with statins or Stopping the drug (>1 mth) , come to endocrine clinic of Imam Reza (AS) hospital were enrolled after consent . The sample size of this study, according to the results of the yicong, and colleagues study , Hs-CRP changes in the power 80 and a maximum Type I error of 0.05 was determined for each group of 93 samples to increase the validity of study , 100 patients for each group determined. The subjects were randomly divided into 2 groups of 100 people. In the first group, statins at high doses (40 mg) and low-dose statin group (10mg) administered. Initial tests : FBS, HbA1C, AST, ALT, ALP, BUN, Cr, TG, Total chol, LDL.HDL and specific tests: Homocysteine , fibrinogen and IL6 and IL1 done at baseline and then repeated 3 months. the effects of high-dose atorvastatin and low-dose atorvastatin after three months of education, on inflammatory factors and clotting factors are measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502226710N5**
Registration date: **2015-05-22, 1394/03/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-22, 1394/03/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

vice chancellor fo research,Tabriz university of Medical sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

Public title

Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with type2 diabetes mellitus

LDL>70 ; age>18y ;TG<500; patients who don't use or stopped statin use (> 1 mth) Exclusion criteria: type 1 diabetes Mellitus; chronic liver disease(liver enzymes more than 3 time the upper limit of normal , B or C Hepatitis); renal failure Cr>2;pregnancy;lactation ; Chronic inflammatory diseases such as rheumatic diseases (rheumatoid arthritis and systemic lupus erythematosus); Patients with a history of anti-inflammatory drugs; In case of muscle pain and increased risk of rhabdomyolysis in patients with CPK elevation; unwillingness to participate in the study.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah Sq

City
Tabriz

Postal code

Approval date
2015-02-09, 1393/11/20

Ethics committee reference number
93168

Health conditions studied

1

Description of health condition studied
type 2 diabetic

ICD-10 code
E10,E11,E1

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
low density Lipoprotein

Timepoint
At baseline and after 3 months of treatment

Method of measurement
Test

2

Description
cholestrol

Timepoint
At baseline and after 3 months of treatment

Method of measurement
test

Secondary outcomes

1

Description
inflammatory markers

Timepoint
At baseline and after 3 months of treatment

Method of measurement
test

2

Description
coagulatory factor

Timepoint
At baseline and after 3 months of treatment

Method of measurement
test

Intervention groups

1

Description
In the first group tablet Atorvastatin (40-80 milligram) daily will be prescribed

Category
Treatment - Drugs

2

Description
In the second group tablet Atorvastatin (10-20 milligram) daily will be prescribed

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Clinic of Imam Reza hospital
Full name of responsible person
Dr. vahide Sadra
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences Daneshgah Square Tabriz
Full name of responsible person
Dr Rashidi
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue,
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences Daneshgah Square Tabriz
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty